IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Jane P. Bearinger, et al.	Examiner: Gregory A. Anderson	
Application No.:	10/781,582	Art Unit: 3773	
Filed:	02/17/2004	Attorney Docket: IL-11213	
TITLE:	**SYSTEM FOR CLOSURE OF A PHYSICAL ANOMALY**		

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANT'S REPLY BRIEF (37 C.F.R. § 1.192)

This Reply Brief is submitted in response to the "Examiner's Answer" mailed August 15, 2011. Appellant's Appeal Brief is relied upon as responding to the issues in the Examiner's Answer; however, Appellant provides this Reply Brief with the following additional responses to specific points in the Examiner's Answer. One copy of the Reply Brief is being transmitted per 37 C.F.R. § 41.37.

STATUS OF CLAIMS

The application as originally filed contained claims 1-35.

The claims on appeal were originally claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 were rejected; however, the rejection of claims 19-21, 25, and 31 was withdrawn in the Examiner Examiner's Answer on page 4, lines 4-6.

Claims 2, 3, 7, 8, 9, 10, 18, 22, 23, 24, 26, 27, 28, 29, 30, and 33 are cancelled.

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal are reproduced in the Appeal Brief Appendix.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed March 11, 2011 states two grounds of rejection. The two grounds of rejection are summarized as follows:

Grounds of Rejection #1 - Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans et al U. S. Patent No. 5,549,633 (hereinafter "Evans") in view of Bleys et al U. S. Patent No. 6,034,149 (hereinafter" Bleys").

Withdrawn Rejections

The Examiner's Answer on page 4, lines 4-6 states that the "following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection of claims 19-21, 25, and 31 over Evans et al. in view of Bleys et al."

Grounds of Rejection #2 - Claims 6, 13, and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys and further in view of Duane et al U. S. Patent No. 5,836,306 (hereinafter" Duane").

Reply to Examiner's Answer Regarding Grounds of Rejection #1

Appellant's Appeal Brief is relied upon as responding to the Examiner's Answer regarding Grounds of Rejection #1; however, Appellant provides the following responses to specific points raised by the Examiner's Answer. The Examiner's Answer in the paragraph that bridges pages 4-5 includes the following statements:

> "Evans et al. discloses an apparatus for closure of an arterial puncture comprising: a closure body 22, the closure body being made of foam formed into a primary shape and compressed into a reduced secondary stable shape and then controllably actuated to that it recovers its primary shape (Figs. 10-12), a delivery catheter 20 adapted to receive the closure body and adapted to deploy the closure body into the physical anomaly, wherein the foam of the closure body in the secondary shape is configured for positioning the closure body within the anomaly (Fig. 10), and wherein the foam is controllably actuated so that it recovers its primary shape with the primary shape being configured to close the anomaly (Fig. 12). Evans et al. further discloses a plunger 28 for controllably actuating the foam and a tube 26. The foam of Evans et al. takes the form of the container it is in, i.e. a tubular shape when it is within the deployment device and a shape conforming to the tissue surrounding the closure body when deployed, and thus has similar shape to that which a flowing fluid would have in the same scenarios. Further, the foam of Evans et al. has a volume larger than the gap in the vascular wall (Fig. 12) when deployed and smaller than the gap (Fig. 9) when being delivered."

Appellant respectfully disagrees with a number of the above statements. Appellant respectfully disagrees with the Examiner's Answer statement: "...a closure body 22, the closure body being made of foam formed into a primary shape and compressed into a reduced secondary

stable shape and then controllably actuated to that it recovers its primary shape (Figs. 10-12)..." Appellant points out that the closure body 22 of the Evans reference is not described as "being made of foam formed into a primary shape and compressed into a reduced secondary stable shape and then controllably actuated to that it recovers its primary shape." The mass or body 22 of the Evans reference is described as "composed of collagen foam" (See Quoted Section Below) and is not Appellant's claim element: "a shape memory polymer (SMP) foam."

> "In accordance with a preferred embodiment of this invention the mass or body 22 is composed of collagen foam, since that material enables blood to readily clot therein, thus expediting hemostasis (blood flow stoppage) when the application is used to prevent the seepage of blood from a percutaneous puncture to a blood vessel or some other interior structure in the body of the being. In particular, the mass is preferably a porous sponge of Type 1 collagen marketed by Collatec, Inc. under the trade name HELISTAT. This material is a natural hemostatic material to provide hemostasis and the elimination of any "weeping" or seeping of blood due to incomplete closure of the puncture site by the sutures, as will be described later. Other hemostatic materials, such as cellulose-based, hemostatic materials manufactured and sold by Upjohn Company under the trademark GELFOAM, can also be used for the mass 22. Other blood clotting materials can be used in lieu of collagen. In fact the material of the mass 22 need not even absorb the blood nor promote blood clotting therein, so long as it is resistant to the passage of a fluid therethrough." (Column 6, lines 32-52 of the Evans Reference)

Appellant also respectfully disagrees with the Examiner's Answer statement that the closure body 22 is: "... adapted to deploy the closure body into the physical anomaly ..." Appellant points out that the closure body 22 of the Evans reference is not described as "adapted to deploy the closure body into the physical anomaly." The mass or body 22 of the Evans reference is described as "adjacent the hole or opening 10B in the wall 10C of the artery." (See Quoted Section Below)

> "... applying that mass of material 22 into an arterial puncture tract 10A extending through the skin and underlying tissue 12 so that the mass 22 is adjacent the hole or opening 10B in the wall 10C of the artery. Alternatively, the mass can be placed on the surface of the skin contiguous with the puncture ..."

Since the Evans reference "mass of material 22 ... is adjacent the hole or opening 10B in the wall 10C of the artery", the Evans reference does not teach or suggest deploying the mass 22 into opening 10B in the wall 10C of the artery. Accordingly, the Evans reference does not teach or suggest Appellant's claim elements and claim limitations in independent claim 1:

> "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,"

> "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall,"

> "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Appellant also respectfully disagrees with the Examiner's Answer statement "...wherein the foam is controllably actuated so that it recovers its primary shape with the primary shape being configured to close the anomaly (Fig. 12)..." The Evans reference "mass of material 22" does not recover any primary shape. Further, the Evans reference mass of material 22 "is adjacent the hole or opening 10B in the wall 10C of the artery" and does not close the anomaly. Accordingly, the Evans reference does not teach or suggest Appellant's claim elements and claim limitations: "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The Examiner's Answer in the first full paragraph on page 6 includes the following statements:

> "It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. by using the shape memory foam of Bleys et al. in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of chemicals to ensure a minimum of leachable substances in contact with the human body as taught by Bleys et al. (Col. 6 ll. 40-51)."

Appellant points out that even if one were to "...modify the device of Evans et al. by using the shape memory foam of Bleys et al..." the combined apparatus still would not be Appellant's claimed apparatus because the combined apparatus would lack Appellant's claim elements and claim limitations: "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," and "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," and "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The combination of the Evans and Bleys references in Grounds of Rejection #1 fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 32, 34, and 35 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #1 should be reversed.

Reply to Examiner's Answer Regarding Grounds of Rejection #2

Appellant's Appeal Brief is relied upon as responding to the Examiner's Answer regarding Grounds of Rejection #2; however, Appellant provides the following responses to specific points raised by the Examiner's Answer. The Examiner's Answer in the first paragraph on page 7 includes the following statements:

> "It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. in view of Bleys et al. with the restraint tube of Duane et al. in order to provide backbleed control during and after placement of a catheter within a patient's vascular system as taught by Duane et al. (Col. 2 ll. 44-49)."

Appellant respectfully disagrees with the above statements. Appellant points out that there would be no reason to modify the Evans reference and the Bleys reference to include "backbleed control." Neither reference gives any reason for the propsed modification. Appellant also points out that even if one were to "…modify the device of Evans and the device of Bleys with the device of Duane, the combined apparatus still would not be Appellant's claimed apparatus because the hypothetical combined apparatus would lack many of Appellant's claim elements and claim limitations. The hypothetically combined apparatus would lack many of Appellant's claim elements and claim limitations of parent claim 1 listed below.

> "a shape memory polymer (SMP) foam,"
>
> "said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},"
>
> "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,"
>
> "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,"
>
> "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall,"

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, "

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall,"

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The Primary Evans reference, the Secondary Bleys reference, and the tertiary Duane reference do not teach or suggest the claim elements and claim limitations of Appellant's claims, the references do not support the rejection of claims 6, 13, and 15 under 35 U.S.C. 103(a). The rejection in Grounds of Rejection #2 should be reversed.

SUMMARY

The claims originally on appeal were claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35. The rejection of claims 19-21, 25, and 31 was withdrawn in the Examiner Examiner's Answer on page 4, lines 4-6. The final claims on appeal are claims 1, 4-6, 11-17, 32, 34, and 35.

Appellant believes that claims 19-21, 25, and 31 should be allowed since the rejection of claims 19-21, 25, and 31 has been withdrawn by the Examiner Examiner's Answer. (Page 4, lines 4-6 of the Examiner Examiner's Answer)

Appellant has demonstrated that claims 1, 4, 5, 11, 12, 14, 16, 17, 32, 34, and 35 are not obvious over the proposed combination of references in Grounds of Rejection #1. Appellant has demonstrated that claims 6, 13, and 15 are not obvious over the proposed combination of references in Grounds of Rejection #2. The rejections in Grounds of Rejection #1 and #2 should be reversed.

It is respectfully requested that claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal be allowed.

Respectfully submitted,

By: 

Eddie E. Scott
Lawrence Livermore National Laboratory
7000 East Avenue, Mail Code L-703
Livermore, CA 94550
Attorney for Appellants
Registration No. 25,220
Telephone No. (925) 424-6897

Date: 10/6/2011